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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,998	10/05/2006	Kai Schiemann	MERCK-3073	6474
23599 7590 11/20/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER CHU, YONG LIANG	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 11/20/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,998	<b>Applicant(s)</b> SCHIEMANN ET AL.	
	<b>Examiner</b> Yong Chu	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 8, 10-12, and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 9, 13 and 16 is/are rejected.
- 7) ☒ Claim(s) 1, 7, 9, 13 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/04/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

Claims 1-16 are pending in the instant application.

### *Information Disclosure Statement*

Applicants' Information Disclosure Statement, filed 10/04/2005 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

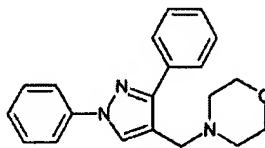
### *Priority*

This Application is a 371 of PCT/EP04/02354 filed on 03/08/2004, which claims foreign priority of Germany 10315573.2, filed on 04/05/2003.

### *Response to Restriction/Election*

Applicant' election with traverse of Group II (Claims 1-7, 9, 13 and 16, wherein X

is CH) and the elected species of Example 8



on page 21 of the

Specification in the reply filed 09/24/2007 is acknowledged. Applicant's traverse on the ground that that patent Office has not established that it would pose an undue burden to examine the full scope of the claimed invention has been fully considered, and are found not persuasive, because the subject matters in Groups I and II of the invention are classified under different classes and subclasses. Group I (wherein X is N) is under classes 514, 548 and 549, and Group II (X is CH) is under 514 and 548. Since the

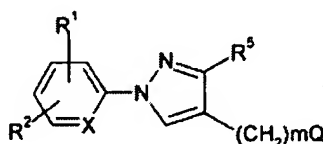
pyrazol moiety is a very common structure full of the prior arts, it has to be bonded to another moiety such as phenyl or pyridine to form a possible special core structure, which corresponding to Group I and Group II. It requires searching and examining individually over different databases. It will poses undue burden to Examiner to examine full scope of the invention. Therefore, the restriction requirement is indeed appropriate, and maintained.

### ***Status of the Claims***

Claims 10-12, and 14-15 are further withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR 1.142(b) due to the restriction requirement.

### **Elected and Examined Subject Matter**

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



A compound of the Formula I according to claim 1,

wherein:

X is CH;

m is 1,2, or 3;

Q is saturated, unsaturated or aromatic mono- or bicyclic heterocyclic radical, which is unsubstituted or mono- or polysubstituted according to Claim 1;

R<sup>5</sup> is a optionally substituted phenyl; and

$R^1$  and  $R^2$  are H.

As a result of the election and the corresponding scope of the invention identified supra, claims 2-6, and the remaining subject matter of claims 1, 7, 9, 13, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups, which are chemically recognized to differ in structure, function, and reactivity. Therefore, claims 1, 7, 9, 13, and 16 will be examined on the merits.

### ***Specification***

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 9, 13, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 7, 9, 13, and 16 contain subject matter, not defined in the specification so as to known the structure of the compounds that are included and/or excluded by the terms "an organic heteroatom-containing radical" in the definition of the "Het" moiety, the term "linear or branched organic radical containg one or more hetero atoms" in the definition of the "Het" moiety,

"a ring-containing group  $-\text{CH}_2\text{O}-$ " in the definition of the "Ar" moiety, and "physiologically tolerated salts" in Claim 1.

Examples and description should be of sufficient scope as to justify the scope of the claims. *Markush* claims must be provided with support in the disclosure for each member of the *Markush* group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A complete disclosure should include a statement of utility. In chemical cases, varying degrees of specificity are required. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound or composition. Incomplete teachings may not be completed by reference to subsequently filed applications see MPEP §608.0(p).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 9, 13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, page 2, the substituent "X" is missed from Claim 1, which renders 1, 7, 9, 13, and 16 indefinite. The Examiner interprets X as CH in light of the Specification. Appropriate correction is required.

In claim 7, the formula IA is incomplete, which renders claim 7 unsearchable. Therefore, it is rejected. Appropriate correction is required without introduce new matter.

Claim 16 is indefinite because it is defined the compounds of formula I. However, there is no formula I in claim 16. Applicant needs to amend the claim as a depend claim to claim 1. Appropriate correction is required.

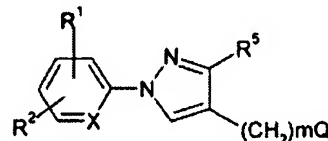
***Claim Rejections - 35 USC § 102(b)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 9, 13, and 16 are rejected under 35 U.S.C. 102 (b) as being anticipated by Caramella et al., Heterocycles, 1995, 40(2), p.515-520 ("Caramella et al.").



Applicants' claims relate to a compound of the Formula I according to claim 1, wherein:

X is CH;

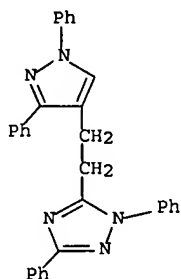
m is 1,2, or 3;

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**Q** is saturated, unsaturated or aromatic mono- or bicyclic heterocyclic radical, which is unsubstituted or mono- or polysubstituted according to Claim 1;

**R<sup>5</sup>** is a optionally substituted phenyl; and

**R<sup>1</sup>** and **R<sup>2</sup>** are H.



Caramella et al. discloses a compound

(CAS RN 165963-83-7)

that anticipates the instantly claimed genus, wherein **X** is CH;

**m** is 2; **Q** is an aromatic monocyclic heterocyclic radical; **R<sup>5</sup>** is a optionally substituted phenyl; and **R<sup>1</sup>** and **R<sup>2</sup>** are H, (see compound 5, page 517). Because the compound anticipated, the composition is also anticipated inherently.

### ***Claim Objections***

Claim 16 is objected to because of the following informalities: a claim should end with a period. The period at end of the claim is missing. Appropriate correction is required.

Claims 1, 7, 9, 13, and 16 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

### ***Conclusion***

- Claims 1, 7, 9, 13, and 16 are objected.
- Claims 1, 7, 9, 13, and 16 are rejected.



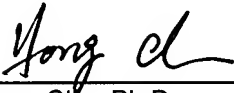
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***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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